Department of Health and Human Services | Public Health Service

Food and Drug Administration
Rockville, MD 20857

MAY 5 2011

Re: IXIARO
Docket No. FDA-2009-E-0416

The Honorable David J. Kappos
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the patent term extension application for U.S. Patent No. 6,309,650 filed by Chiel Jedang Corp., and Walter Reed Army Institute of Research under 35 U.S.C. § 156. The patent claims IXIARO (Japanese Encephalitis Virus, Vaccine Inactivated, Adsorbed), which was assigned biologics license application (BLA) B125280/0.

In the September 9, 2010, issue of the Federal Register (75 Fed. Reg. 54888), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before March 8, 2011, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: William T. Christiansen, Ph.D.
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